

ATTACHMENT B

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Eberhard FRITZ and Gerd PHILLIPPS

Appln. No.:

Filed: December 18, 2001

For: RADIATION SOURCE FOR ENDOVASCULAR RADIATION TREATMENT

Attorney Docket No.: 3993.002

PRELIMINARY AMENDMENT

Attn: Box PCT
Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application,
please amend the application as follows:

IN THE CLAIMS (CLEAN VERSION):

Please cancel original claims 1-22 and add the following new
Claims 23-48 as follows:

23. A radiation source for use in endovascular radiation treatment which comprises one or more seeds (treating elements) comprising a radiation emitting element and means for containment of said radiation emitting element, wherein said seeds are in an elongated container having at least one deflection site.
24. The radiation source of claim 23, wherein the elongated container is a hollow cylinder.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

25. The radiation source of claim 23, wherein the container is made from a highly flexible material.
26. The radiation source of claim 25, wherein said flexible material is selected from the group consisting of Ni-Ti-alloy and aluminum alloy
27. The radiation source of claim 26, wherein said flexible material is selected from the group consisting of Nitinol and Tinal alloy BB.
28. The radiation source of claim 23, wherein the one or more deflection site(s) comprise perforation patterns.
29. The radiation source as in claim 28, wherein said patterns are laser perforations of the container.
30. The radiation source of claim 23, wherein the one or more deflection site(s) comprise multiple helical openings in the tube.
31. The radiation source of claim 23, wherein the seeds comprise rounded or spherical end caps on one or both ends.
32. The radiation source of claim 23, wherein the seeds are separated from each other by at least one spacer.
33. The radiation source of claim 32, wherein said spacer is in form of a sphere.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

34. The radiation source of claim 23, wherein the seeds are spaced from each other and fixed to the inner wall of the container.
35. The radiation source of claim 23, wherein said means for containment is a metallic capsule.
36. The radiation source of claim 23, wherein the radiation emitting element comprises any α -, β - and/or γ -emitting substance.
37. The radiation source of claim 36, wherein the radiation emitting element comprises one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} , Ru^{106} , P^{32} , Ir^{192} , Re^{188} , W^{188} and I^{125} .
38. An apparatus for endovascular radiation treatment, comprising an elongated catheter having a proximal end portion, a distal end portion and a single lumen for receiving a radiation source, optionally a guide wire and a second lumen therefore, and a radiation source which comprises one or more seeds (treating elements) comprising a radiation emitting element and means for containment of said radiation emitting element, wherein said seeds are in an elongated container having at least one deflection site.
39. The apparatus of claim 38, wherein the radiation source comprises a radiation emitting element comprising one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} ,

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

Ru^{106} , P^{32} , Ir^{192} , Re^{188} , W^{188} and I^{125} contained in a container made from a highly flexible material.

40. The apparatus of claim 38, further comprising a containment vessel for radiation protection.
41. The apparatus of claim 38, further comprising a magnetic means.
42. The apparatus of claim 38, further comprising an x-ray fluoroscopy device.
43. A method for endovascular radiation treatment comprising the steps of
 - (a) directing an elongated catheter, having a proximal end portion, a distal end portion and a lumen extending therebetween for receiving a radiation source, to the selected site to be treated preferably by way of a guide wire in a separate lumen;
 - (b) introducing a radiation source into the catheter at its proximal end portion, which radiation source comprises one or more seeds (treating elements), wherein said seeds are in an elongated container having at least one deflection site;
 - (c) moving said radiation source to said distal end portion preferably by way of a transfer wire;
 - (d) maintaining said radiation source at said distal end portion for a determined period of time; and
 - (e) retracting said radiation source to the proximal end portion preferably by use of a transfer wire.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

44. The method of claim 43, wherein moving and/or retracting in steps (c) and/or (e) is achieved by pushing or pulling the radiation source.
45. The method of claim 43, wherein said movement in step (c) is achieved by pushing and said movement in step (e) is achieved by pulling said radiation source.
46. The method of claim 43, wherein the radiation source is linked to a transfer wire at its proximal end and moving in step (c) occurs by pushing the transfer wire into the catheter and retracting in step (e) occurs by pulling the transfer wire out of the catheter.
47. The method of claim 43, wherein a radiation source comprising a magnetic elongated container is used and movement in steps (c) and/or (e) is achieved by magnetically pushing and/or pulling the radiation source using a transfer wire comprising a magnet or using an external magnetic means.
48. The method of claim 43, wherein the radiation source comprises a radiation emitting element comprising one or more radioactive materials selected from the group consisting of Cs¹³⁷, Co⁵⁷, Sr⁸⁹, Y⁹⁰, Au¹⁹⁸, Pd¹⁰³, Se⁷⁵, Sr⁹⁰, Ru¹⁰⁶, P³², Ir¹⁹², Re¹⁸⁸, W¹⁸⁸ and I¹²⁵ contained in a container made from a highly flexible material.

REMARKS

The claims have been amended in order to eliminate multiple dependent claims and claims improperly depending from multiple dependent claims, and to otherwise conform the claims to U.S.

U.S. Application No.:
PRELIMINARY AMENDMENT

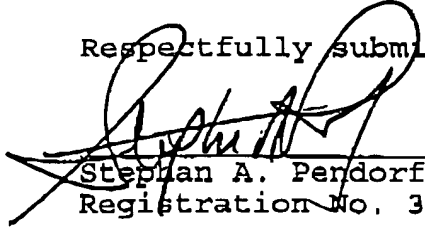
Attorney Docket: 3993.002

practice. Care has been taken to ensure that no new matter is added to the text.

Entry and favorable consideration prior to consideration are respectfully requested.

Respectfully submitted,

PENDORF & CUTLIFF
P.O. Box 20445
Tampa, Florida 33622-0445
(813) 886-6085


Stephan A. Pendorf
Registration No. 32,665

Date: December 18, 2001

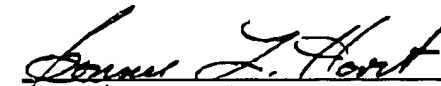
EXPRESS MAIL CERTIFICATE

"EXPRESS MAIL" MAILING LABEL NUMBER: EL568148065US

DATE OF DEPOSIT: December 18, 2001

I HEREBY CERTIFY that the foregoing Preliminary Amendment and a stamped receipt post card are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated and is addressed: ATTN: Box PCT, Commissioner of Patents and Trademarks, Washington, D.C. 20231.

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 16-0877.


Bonnie L. Horst

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

The Examiner is requested to accept the marked-up version as it is based on the previous version, which when modified as below, produces the clean version submitted with the current amendment.

Please amend the claims as follows:

Please delete original Claims 1-22.

Please add the following new Claims 23-48:

- 23. A radiation source for use in endovascular radiation treatment which comprises one or more seeds (treating elements) comprising a radiation emitting element and means for containment of said radiation emitting element, wherein said seeds are in an elongated container having at least one deflection site.
24. The radiation source of claim 23, wherein the elongated container is a hollow cylinder.
25. The radiation source of claim 23, wherein the container is made from a highly flexible material.
26. The radiation source of claim 25, wherein said flexible material is selected from the group consisting of Ni-Ti-alloy and aluminum alloy
27. The radiation source of claim 26, wherein said flexible material is selected from the group consisting of Nitinol and Tinal alloy BB.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

28. The radiation source of claim 23, wherein the one or more deflection site(s) comprise perforation patterns.
29. The radiation source as in claim 28, wherein said patterns are laser perforations of the container.
30. The radiation source of claim 23, wherein the one or more deflection site(s) comprise multiple helical openings in the tube.
31. The radiation source of claim 23, wherein the seeds comprise rounded or spherical end caps on one or both ends.
32. The radiation source of claim 23, wherein the seeds are separated from each other by at least one spacer.
33. The radiation source of claim 32, wherein said spacer is in form of a sphere.
34. The radiation source of claim 23, wherein the seeds are spaced from each other and fixed to the inner wall of the container.
35. The radiation source of claim 23, wherein said means for containment is a metallic capsule.
36. The radiation source of claim 23, wherein the radiation emitting element comprises any α -, β - and/or γ -emitting substance.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

37. The radiation source of claim 36, wherein the radiation emitting element comprises one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} , Ru^{106} , P^{32} , Ir^{192} , Re^{188} , W^{188} and I^{125} .
38. An apparatus for endovascular radiation treatment, comprising an elongated catheter having a proximal end portion, a distal end portion and a single lumen for receiving a radiation source, optionally a guide wire and a second lumen therefore, and a radiation source which comprises one or more seeds (treating elements) comprising a radiation emitting element and means for containment of said radiation emitting element, wherein said seeds are in an elongated container having at least one deflection site.
39. The apparatus of claim 38, wherein the radiation source comprises a radiation emitting element comprising one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} , Ru^{106} , P^{32} , Ir^{192} , Re^{188} , W^{188} and I^{125} contained in a container made from a highly flexible material.
40. The apparatus of claim 38, further comprising a containment vessel for radiation protection.
41. The apparatus of claim 38, further comprising a magnetic means.
42. The apparatus of claim 38, further comprising an x-ray fluoroscopy device.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

43. A method for endovascular radiation treatment comprising the steps of
- (a) directing an elongated catheter, having a proximal end portion, a distal end portion and a lumen extending therebetween for receiving a radiation source, to the selected site to be treated preferably by way of a guide wire in a separate lumen;
 - (b) introducing a radiation source into the catheter at its proximal end portion, which radiation source comprises one or more seeds (treating elements), wherein said seeds are in an elongated container having at least one deflection site;
 - (c) moving said radiation source to said distal end portion preferably by way of a transfer wire;
 - (d) maintaining said radiation source at said distal end portion for a determined period of time; and
 - (e) retracting said radiation source to the proximal end portion preferably by use of a transfer wire.
44. The method of claim 43, wherein moving and/or retracting in steps (c) and/or (e) is achieved by pushing or pulling the radiation source.
45. The method of claim 43, wherein said movement in step (c) is achieved by pushing and said movement in step (e) is achieved by pulling said radiation source.
46. The method of claim 43, wherein the radiation source is linked to a transfer wire at its proximal end and moving in step (c) occurs by pushing the transfer wire into the catheter and retracting in step (e) occurs by pulling the transfer wire out of the catheter.

U.S. Application No.:
PRELIMINARY AMENDMENT

Attorney Docket: 3993.002

47. The method of claim 43, wherein a radiation source comprising a magnetic elongated container is used and movement in steps (c) and/or (e) is achieved by magnetically pushing and/or pulling the radiation source using a transfer wire comprising a magnet or using an external magnetic means.
48. The method of claim 43, wherein the radiation source comprises a radiation emitting element comprising one or more radioactive materials selected from the group consisting of Cs^{137} , Co^{57} , Sr^{89} , Y^{90} , Au^{198} , Pd^{103} , Se^{75} , Sr^{90} , Ru^{106} , P^{32} , Ir^{192} , Re^{188} , W^{188} and I^{125} contained in a container made from a highly flexible material.--